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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,175	HENOT ET AL.	
	Examiner	Art Unit	
	Sharon Wen	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-29* is/are pending in the application.

4a) Of the above claim(s) *24-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-23 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/16/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location of the examiner of this application in the PTO has changed. To aid in the correlating any papers for this application, all further correspondence regarding this application should be directed to Sharon Wen, Group Art Unit 1644, Technology Center 1600.

Election/Restrictions

2. Applicant's election with traverse of Group I and allergic reaction, nucleotide triphosphates and grass allergen as the species in the reply filed on 05/18/2007 is acknowledged.

The traverse is on the ground that Duchateau does not disclose where in the body the pharmaceutical formulation is absorbed; and that the present claims recite sublingual and buccal administration which allow absorption in the mouth mucosa.

This is not found persuasive because the feature "sublingual, buccal or enteric administration" recited in the present claims is an intended uses as the claims are directed to a pharmaceutical composition comprising one or more substances. Therefore this feature is not required by all the claims of the invention.

Also, giving the claims the broadest reasonable interpretation, the claims read on a pharmaceutical composition "which allows absorption of at least one substance in the mouth mucosa" (page 5 of the specification). The claims do not specify any level of "absorption", thus the claims read on any measurable aborption. The oral composition taught by Duchateau et al. would have some level of absorption and therefore meets the limitation.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-14 have been canceled.

Claims 15-29 are pending.

Claims 24-26 have been withdrawn from further consideration under 37 CFR § 1.142(b) as being drawn to non-elected Groups and/or Species.

Claims 15-23 and 27-29 are currently under examination as they read a pharmaceutical composition.

Priority

4. The effective priority date for claims 15-23 and 27-29 are deemed to be the filing date of provisional application USSN 60/530,629, i.e. 12/19/2003

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

Applicant is requested to amend the first line of the specification to reflect Applicant's claim for priority.

Specification

5. Applicant is requested to review the application for the use of trademarks, embedded hyperlinks and/or other form of browser-executable code (e.g. see page 4 line 20 of specification).

Trademark should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Information Disclosure Statement

6. Applicant's IDS, filed on 12/16/2005, is acknowledged, and has been considered.

Claim Rejections - 35 USC § 112 second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 2173.05(h).

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any New Matter. See MPEP § 714.02 and 2163.06.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 15-21, 23 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Pradalier et al. (Allergy 1999, 54:819-828, see entire document) as evidenced by Ball et al (U.S.Patent 6,559,120, see entire document)..

Pradalier et al. teach a pharmaceutical composition comprising grass allergens wherein the composition is in a sublingual formulation (see entire document, in particular, page 819 Methods, page 821 sections under Allergen preparations and Treatment).

The reference teach making the pharmaceutical composition comprising grass allergens in the range of 0.001 to 1000 µg or 1 to 100 µg (see page 821, section under Treatment). The reference discloses that cumulative allergen doses in the active treatment group was about 11,000 IF corresponding to 0.935 mg or 935 µg; and that single sublingual tablet contains 100 IR, or 9.35 µg of allergen. Therefore these amounts of allergen taught by the reference anticipate the ranges recited in claims 16-17.

Although the reference is silent on the substance (i.e. grass pollen) being a peptide (claim 19), grass allergens are well known to be proteins/peptides by the ordinary artisan in the art at the time of the invention was made as evidence by Ball et al. (see column 1, lines 62-65). Therefore the grass pollen taught by Pradalier et al, under the broadest reasonable interpretation, reads on peptides.

Similarly, under the broadest reasonable interpretation, a composition formulated for sublingual administration as taught by the reference would also be in buccal or enteric formulation (claims 28-29).

Given the extract formulation of the prior art, the claimed peptides having a molecular weight less than 30 or 10 kDa would have been inherent in the prior art grass pollen extract, as extracts were known to be a solution of essential constituents of a complex material (claims 20-21).

It is noted that the claims provide intended uses for the pharmaceutical composition, i.e. "for sublingual, buccal or enteric administration" and "induces graft rejection, allergic reaction or autoimmune disease" but such intended uses do not distinguish from the pharmaceutical composition in the art. See e.g. MPEP § 2114.

Furthermore, the present claims are product-by-process claims because of the recitation "substance obtainable by hydrolysis with chymotrypsin or any other protease". Since the reference teach a pharmaceutical composition comprising the one or more substances, i.e. grass allergens, the same substances obtainable by hydrolysis with chymotrypsin or any other protease would also be anticipated by the reference.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

11. Claims 15 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by McKnight et al. (U.S. Patent 6,319,679 B1, see entire document).

Because claim 15 is a product-by-process claim (see above), the same polypeptide obtainable by hydrolysis would be anticipated by the reference. Additionally, as stated above, the claims provide intended uses for the pharmaceutical composition, i.e. "for sublingual, buccal or enteric administration" and "induces graft rejection, allergic reaction or autoimmune disease" but such intended uses do not distinguish from the pharmaceutical composition in the art. See e.g. MPEP § 2114.

Therefore, under the broadest reasonable interpretation, the present claims read on a pharmaceutical composition comprising one or more substance and comprising additionally nucleoside triphosphates.

McKnight et al. teach a pharmaceutical composition comprising a substance (a polypeptide) and further comprising a nucleoside triphosphates (see column 5, lines 10-23 and claims 1-11).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 15-23 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pradalier et al. (Allergy 1999, 54:819-828) in view of Ćirković et al. (Allergy 1999, 54:128-123), Malley (U.S. Patent 4,215,036) and Marx (U.S. Patent 5,898,037).

The Pradalier et al. reference has been discussed, supra.

The Pradalier et al. reference does not explicitly teach that the substance, being a grass allergen, has a molecular weight of less than 30 kDa or less than 10 kDa, per se.

However, Ćirković et al. teach that it is well known in the art to make low-molecular weight allergens in a pharmaceutical composition (see entire document, in particular, see page 128, Background, page 129 Material and methods). In particular, Ćirković et al. teach how to modify orchard grass pollen (a species of grass allergen also taught by Pradalier et al.) to obtain low-molecular weight in the 30 kDa range (see Figure 1 and page 132 Molecular weight distribution).

In addition, grass allergens with even lower molecular weight are well known in the art as evidence by Malley wherein the grass allergen has been modified to have molecular weight of less than 10 kDa (see entire document, in particular, see column 1, lines 56-60).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to make a pharmaceutical composition comprising grass allergen such as orchard grass pollen as taught by Pradalier et al. and modify the allergen to obtain a low molecular weight of less than 30 or 10 kDa as taught by Ćirković et al. and Malley.

Furthermore, one of ordinary skill would have been motivated to make a pharmaceutical composition comprising a low-molecular weight allergen because of the teaching by Ćirković et al. on that low molecular weights make the allergen able to cross biological membrane thus suitable for sublingual administration (page 129, left column, paragraph 3) and that the modification procedure used to make low molecular weight allergen yields allergens of good performance in immunotherapy (page 134, left column, lines 1-2).

The Pradalier et al. reference does not teach a pharmaceutical composition further comprising nucleoside triphosphate, per se.

However, nucleoside triphosphate is a well known adjuvant used in immunotherapy associated with allergic reactions as evidence by Marx (see entire document, in particular, Detailed Description of Preferred Embodiments). Specifically, Marx teaches that ATP, a nucleoside triphosphate, is a preferred adjuvant in a composition suitable for treating allergic condition (see column 5, lines 4-10 and lines 52-55).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to make a pharmaceutical composition comprising grass allergen such as orchard grass pollen as taught by Pradalier et al. and further comprising nucleoside triphosphates such as ATP as taught be Marx.

Given the teaching by Pradalier et al. that the aim of the sublingual immunotherapy with grass allergens is to elicit IgE and IgG production (page 827, right column, second paragraph), and that the teaching by Marx that ATP is a preferred adjuvant for treating allergic conditions (see column 5, lines 4-10 and lines 52-55), one of ordinary skill would have been motivated to add nucleoside triphosphate such as ATP in a pharmaceutical composition comprising grass allergen for sublingual immunotherapy.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Wen whose telephone number is (571) 270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Wen Ph.D.
Patent Examiner
July 19, 2007

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7/21/07